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Remarks: The appeal brief (in triplicate) is being filed in response to the November 28, 2003 Notification of Non-Compliance with 37 CFR 1.192(c).

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Date	December 18, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant : Rasche et al.

Serial No. : 09/829,007 Examiner: John SOTOMAYOR

Filed : April 10, 2001 Group Art Unit: 3714

For : METHOD AND APPARATUS FOR EDUCATING ASTHMA SUFFERERS AND CAREGIVERS

APPELLANT'S BRIEF ON APPEAL

MS Appeal Brief - Patents
Commissioner of Patents
Alexandria, VA 22313-1450

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APPELLANT'S BRIEF UNDER 37 CFR 1.192

A Notice of Appeal from the final rejection of claims 1-28 and 35-40 for the above-captioned U.S. patent application was filed on July 21, 2003 along with the required filing fee. Appellants hereby file a Brief of Appeal under 37 CFR1.192 (in triplicate) together with the required brief filing fee of $330.00 under 37 CFR 1.17(c). Concurrently filed with this Appeal Brief is a petition for extension of time for the second month and the extension fee for the second month as a petition was filed on October 21, 2003 for the first month of time with the respective fee. The Brief of Appeal under 37 CFR1.192 filed on October 21, 2003 was not accompanied by the requisite brief filing fee.

The Examiner issued a Final Office Action dated April 21, 2003. Appellants hereby file this Brief of Appeal (in triplicate) in response to the Examiner's rejections.

1. Real Party in Interest (37 CFR 1.192(c)(1)

The real party in interest in this appeal is the United States Government, as represented by the Secretary of the Army.

2. Related Appeals and Interferences (37 CFR 1.192(c)(2))

There are no appeals or interferences related to the above-captioned application which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

3. Status of the Claims (37 CFR 1.192(c)(3)

This application was originally filed as U.S. Application No. 09/829,007 on April 10, 2001. The '007 application included claims 1-34. In an Amendment filed on February 3, 2003, claims 29-34 were cancelled, claims 5, 10, 11, and 16 were amended, and claims 35-40 were added. In a Response after Final and Reply filed on June 23, 2003, no claims were cancelled, amended, or added. As such, claims 1-28 and 35-40 are now pending in the present application.

The pending claims were finally rejected in an Office Action mailed on April 21, 2003. Of these, claims 1, 6, 16, and 35 are independent. Appellants filed a Notice of Appeal on July 21, 2003. In an Advisory Action dated July 7, 2003, the Examiner noted that Applicant's arguments were considered, but they were not persuasive according to

the Examiner. Appellants hereby submit this Brief of Appeal under 37 CFR 1.192. A copy of the claims on appeal can be found in the attached Appendix I.

4. Status of Amendments (37 CFR 1.192(c)(4)

In an Amendment and Reply filed on February 3, 2003, claims 29-34 were cancelled, claims 5, 10, 11, 16, 21 and 22 were amended, and claims 35-40 were added. This Amendment has been entered. As such, claims 1-28 and 35-40 are pending in the present application ("the pending claims").

5. Summary of the Invention (37 CFR 1.192(c)(5))

Generally, the present invention defines an asthma assessment and education system and method. *See* Application, Page 10, Paragraph 45.[1] The invention may be embodied in multimedia software, for example. The invention allows for interaction between a user such as a healthcare practitioner or asthma patient and the software. *See id.* For example, to accomplish such interaction, the invention may include an interface, a question database, a memory, a scoring calculator, a score matcher, a summary creator, and an education database. *See* Application, Page 10, Paragraph 46. The interface displays questions from the question database for the user to answer and also displays the answers to the user's questions. The questions and answers for a user questioning and answering session can either be stored in memory or can be provided directly to the scoring calculator. *See* Application, Page 11, Paragraph 48. The invention includes several indicators such as the severity of a patient's asthma, the compliance of the patient, and/or limitations experienced by the patient due to asthma. *See id.* A score is maintained by the scoring calculator for each indicator being accumulated. In other words, a score is accumulated for at least one indicator. *See id.*

The score is based on an accumulation of numerical values for answers to questions asked of the user. Each question has a set of answers with each answer having a numerical value assigned to it as illustrated, for example, in Figures 5-8. When a question is asked that is connected to a particular indicator, then the score for that indicator is increased by a numerical value associated with the answer given by the user. *See* Application, Page 12, Paragraph 51. Sometimes, a question is connected to

[1] Page and paragraph numbers refer to numbers as filed in the original patent application.

multiple indicators. In this case, then the score for each of the multiple indicators is increased by the numerical value associated with the answer given by the user.

After the user completes the questions, the scoring calculator will supply the tallied scores to the score matcher. *See id.* The score matcher then rates the received scores based on predetermined criteria to provide level(s) for the respective indicator(s). For example, a tallied score for the indicator representing "severity of a patient's asthma" may happen to be 1. This accumulated score is then correlated to at least one indicator level. *See* Application, Page 13, Paragraph 51.

The indicator level is determined using a scale that has indicator levels assigned to different indicator scores as illustrated in Figures 5-8 of the application and as discussed in paragraphs 76-79, for example. If the score for the asthma severity score is 5, then the indicator level would be mild persistent asthma. *See* Application, Page 18, Paragraph 76. In an embodiment where the user is able to adjust the indicator level (for example, claims 8 and 37), the user could change "mild persistent asthma" to "mild intermittent asthma" or "moderate persistent asthma." *See* Application, Page 17, Paragraph 73. This adjustment occurs after the indicator score has been correlated to the indicator level after the questions have been asked. *See id.*

In embodiments, the score matcher then provides the level rating to the summary creator. The summary creator provides a summary of the collected information through the interface to the user. Thus, in the example above, based on the indicator level having a score of "1," the summary creator would report the indicator level of the patient (the patient is suffering from mild intermittent asthma). In embodiments, the invention also includes an education database. The education database interacts with the interface to provide written materials, multimedia presentations, and/or other information about asthma. *See Application*, Page 12, Paragraph 50.

As previously described, the invention also presents a method whereby a patient's asthma is assessed and education is provided. According to the method, the user is asked a question, an answer to the question is received, the answer to the question is stored, and a score is maintained for each of the indicators previously discussed. This process is repeated for each question. After the user has completed the questions, each indicator score is matched with an indicator level. *See* Application,

Page 12, Paragraph 51 – Page 14, Paragraph 53. Finally, based on the score of the indicator, an assessment report is provided for the user via the interface. *See* Application, Page 13, Paragraph 52. *See also* Application, Figures 1 and 2(a).

The invention provides an efficient and accurate scoring system and method that allows for improved treatment of asthma patients. The performed assessment of the present invention may be repeated during each visit by the patient to the doctor to provide an indication as to the effectiveness of the chosen therapy in combating the patient's asthma. *See* Application, Page 5, Paragraph 20.

6. Issues (37 CFR 1.192(c)(6))

(1) Whether claims 1, 4-7, 10, and 12-15 are patentable under 35 U.S.C. §102(e) over U.S. Patent No. 6,283,923 B1 to Finkelstein *et al.*

(2) Whether claim 2 is patentable under 35 U.S.C. § 103(a) over Finkelstein *et al.* in view of U.S. Patent No. 5,879,163 to Brown *et al.*

(3) Whether claim 3 is patentable under 35 U.S.C. § 103(a) over Finkelstein *et al.* in view of U.S. Patent No. 5,879,163 to Brown *et al.*

(4) Whether claim 8 is patentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,283,923 B1 to Finkelstein *et al.*

(5) Whether claims 9 and 19 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,283,923 B1 to Finkelstein *et al.*

(6) Whether claim 11 is patentable under 35 U.S.C. § 103(a) over Finkelstein *et al.* in view of U.S. Patent No. 6,375,469 to Brown.

(7) Whether claims 16, 17, 18, 20, 21, 23, 24, 25, 26, 27, and 28 are patentable under 35 U.S.C. §102(e) over U.S. Patent No. 6,283, 923 B1 to Finkelstein *et al.*

(8) Whether claim 22 is patentable under 35 U.S.C. §102(e) over U.S. Patent No. 6,283,923 B1 to Finkelstein *et al.*

(9) Whether claims 35 and 38-40 are patentable under 35 U.S.C. § 103(a) over Finkelstein *et al.* in view of U.S. Patent No. 6,375,469 to Brown.

(10) Whether claim 36 is patentable under 35 U.S.C. §103(a) over Finkelstein *et al.* in view of U.S. Patent No. 6,375,469 to Brown.

(11) Whether claim 37 is patentable under 35 U.S.C. § 103(a) over Finkelstein *et al.* in view of U.S. Patent No. 6,375,469 to Brown.

7. Grouping of the Claims (37 CFR 1.192(c)(7))

The claims have been rejected in the following groups:

(1) Claims 1, 4-8, 10, 12-18, and 20-28;

(2) Claims 9 and 19;

(3) Claims 2 and 3; and

(4) Claims 11 and 35-40.

Applicants submit that the claims of group 2 stand or fall together. The claims in groups 1, 3, and 4 do not stand or fall together based on the rationales expressed in the Argument section below. *See* 37 CFR 1.192(c)(7) and MPEP §1206, p. 1200-10. The group 1 claims are divided into sub-groups: a) 1, 4-7, 10, and 12-15; b) 8; c) 16, 17, 18, 20, 21, 23, 24, 25, 26, 27, 28; and d) 22 as these claim sub-groups are separately patentable from each other. The group 2 claims 9 and 19 are separately patentable over each other. The group 4 claims are divided into sub-groups e) 11; f) 35 and 38-40; g) 36; and h) 37 as these claim sub-groups are separately patentable over each other.

8. Argument (37 CFR 1.192(c)(8))

A. Rejection of Claims under 35 U.S.C. §102(e)

In a Final Office Action dated April 21, 2003, the Examiner rejected claims 1, 4-8, 10, 12-15, 16-18, and 20-28 under 35 U.S.C. § 102(e) as being anticipated by U.S. patent No. 6,283,923 B1 to Finkelstein *et al.* (Finkelstein). Appellants' remarks focus mainly on the independent claims, as any claim which depends from a patentable independent claim is also patentable by virtue of its dependency. *See* 35 U.S.C. § 112 (4).

It is well known that a claim is anticipated only if each and every element in the claim is present, either expressly or inherently, in a single prior art reference. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989) (citations omitted). In this regard, Appellant respectfully submits that the

invention as claimed includes elements not expressly or inherently described in Finkelstein.

Appellants submit that claims 1, 4-8, 10, 12-15, 16-18, and 20-28 of the present invention are patentable under 35 U.S.C. §102(e), as not every feature of these claims is present in Finkelstein, the applied reference. Applicants have divided these claims into four sub-groups (a: 1, 4-7, 10, 12-15; b: 8; c: 16-18, 20, 21, 23-28; and d: 22), which are submitted as being separately patentable.

The four sub-groups are based in part on three independent claims 1, 6, and 16, which are separately patentable. Claim 1 is a means-plus-function claim that is grouped with method claim 6 both of which relate to asthma assessment, which are submitted as being separately patentable from claim 16 that recites a method for performing an asthma assessment. Claim 16 is based on statements in the advisory action that indicated the possibility of the wherein clause providing a clear basis for patentability with the recitation of "for each of the at least one indicator, there is at least answers to two questions that will result in the indicator." Claim 8 is separately patentable because it is not obvious to allow the user to adjust the result one level to provide a better correlation to a subjective assessment, and this recitation is not present in any of the independent claims 1, 6, and 16. Claim 22 is separately patentable because it is not obvious in view of the relied upon art in this rejection to provide educational material as part of the method recited in claim 16.

a. Claims 1, 4-7, 10, and 12-15

Claims 1, 4, and 5 use means-plus-function language to recite the elements included within "a system for scoring an asthma survey for a patient based on information entered by a user regarding the patient." The system includes means for questioning the user regarding the patient, means for accumulating a score for at least one indicator based on answers entered by the user to the questions, means for correlating the accumulated score to at least one indicator level, and means for informing the user of the at least one indicator level from the correlating means.

Means-plus-function language is examined to encompass the "broadest reasonable interpretation" within the constraints of 35 U.S.C. § 112, sixth paragraph. *See In re Donaldson*, 16 F.3d 1189, 1195, 29 USPQ.2d 1845 (Fed. Cir. 1994), *rev'd en*

banc. The U.S. Patent & Trademark Office "may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination." *Id.*; *In re Graves*, 69 F.3d 1147, 36 USPQ2d 1550 (Fed. Cir. 1997).

Claim 1 recites a "means for questioning the user regarding the patient." The specification discloses this as asking a series (or set) of questions of the user regarding the patient during one setting. *See, e.g.*, Application, Page 12, Paragraph 51 and Figures 5-8. *See also*, Application, Page 4, Paragraphs 11 and 12. The specification further states that "the assessment may be utilized during each visit to the doctor . . . or even at regular intervals by the patient at home." *See* Application, Page 15, Paragraph 57. This would imply that the assessment is completed during one setting. The Final Office Action makes reference to published paragraphs 14 and 15 (paragraphs 11 and 12 in the original application) for using the phrase "repeating the questions asked;" however, this is misplaced since both paragraphs state that a set of steps is repeated for each question of an assessment and parallel the language recited in original claims 6 and 16. Given the statements in paragraphs 11 and 12 of the original application, Appellant is unsure of why there would be a belief that the assessment would be stopped and started again with questions being repeated.

Claim 1 also recites a "means for accumulating **a score** for at least one indicator **based on answers** entered by the user to the **questions**" (emphasis added) as discussed, for example, in connection with step 840 in paragraph 54 and illustrated by the score blocks in Figures 5-8. Contrary to the first full paragraph on page 10 of the Final Office Action, claim 1 clearly states that the indicator score is based on multiple answers, and therefore it is correct to state that the indicator score is based on multiple criteria or in the case of Finkelstein multiple symptoms.

On the other hand, Finkelstein appears to disclose asking individual questions on a variety of topics as illustrated in region 340 in Figure 3. *See* Finkelstein, col. 8, lines 54-57. Finkelstein continues by stating that "[e]ach answer is graded according to a predetermined scale, usually 0 to 3." For example, wheezing is graded as 0 (none, no wheezing), 1 (mild wheezing), 2 (moderate wheezing), or 3 (severe wheezing). *See* Col. 8, lines 57-60. The fundamental difference is that Finkelstein discloses setting a textual level to an individual symptom, but not combining answers to a set of conditions

to produce a textual level for a set of conditions. Finkelstein's compiling of scores for a particular symptom over a period of days does not anticipate the accumulating means of the present invention, because the compilation of scores in Finkelstein is for individual symptoms. There is no disclosure of combining symptoms (or answers to multiple questions) to determine, for example, a severity level, a compliance level, and a performance level based upon a set of answers to a set of questions.

Finkelstein also does not anticipate "means for correlating the accumulated score to at least one indicator level," because in part Finkelstein does not teach or suggest the accumulating means that handles the indicator score and accumulates it in claim 1.

Claim 1 then concludes by reciting a "means for informing the user of the at least one indicator level from said correlating means" and this is discussed, for example, in connection with step 870 in paragraph 55. The Final Office Action cites col. 3, lines 40-43 of Finkelstein to anticipate the informing means; however, this reliance appears to be misplaced since the citation discusses displaying the information remote from the person who entered the information, which in Finkelstein is the patient. On page 10 of the Final Office Action, reference is made to columns 8 and 9 of Finkelstein, which further support the concept that the information is displayed remote from the user ("display region 330 is also helpful to the physician," column 8, line 14). Column 4 at lines 41-45, states that "[t]est results are generated ... and disseminated in a timely manner via selectable data links 50 ... to the patient at the remote monitoring station 20." However, Finkelstein uses "test results" to refer to physical test data such as FVC data, and not symptom diary information. *See* col. 5, lines 24-26;[2] and col. 9, lines 44-51. Displaying symptom diary information remote from the patient who is the user is unable to anticipate the recited "means for informing the user."

Claims 6, 7, 10, and 13 relate to a method for assessing asthma patients. The method includes the steps of asking a question, receiving an answer to the question, incrementing a score for at least one indicator based on the answer to the question, correlating each of the at least one indicator score to a corresponding at least one indicator level, and providing the at least one indicator level. This series of steps is repeated for each question asked of the user.

[2] This citation distinguishes between symptom diary data and self-test data (or test data). *Id.*

Independent claim 6 states that for each question in an assessment, a series of steps is performed including "incrementing a score for at least one indicator based on the answer to the question." Finkelstein discloses grading the answer to a symptom diary question against a scale (col. 8, lines 53-60), and does not disclose the incrementing step. In Finkelstein, there is no reason to perform such a step, as each symptom diary question is graded individually. Thus, there is no need to increment an indicator score based on the answer to a question as recited in claim 6.

In the Final Office Action there is reference made to trendpft 534 (trend analysis routine) for teaching incrementing scores. Included in the microfiche portion of Finkelstein is the code for this routine. *See* Finkelstein, cols. 175-198. Cols. 177-178 show that the variables that are available for trend analysis include FVC (Forced Vital Capacity), FEV1 (Forced Expiratory Volume), and FEF25-27% (Forced Mid-Expiratory Flow), all of which are physical data measurements recorded by medical equipment and thus are not subjected to being incremented as part of an indicator score to determine an indicator level. Trend analysis is used to examine medical test data not for subjective data like that contained in the symptom diary in Finkelstein. Finkelstein also does not anticipate "correlating each of the at least one indicator score to a corresponding at least one indicator level," as claimed in claim 6, because in part, Finkelstein does not teach or suggest the indicator score incremented in claim 6. For these reasons, Appellants respectfully submit that claim 6 is patentable over Finkelstein, as Finkelstein does not disclose each and every element of claim 6.

Claim 7 depends from claim 6 and further recites "informing the user of the at least one indicator level." The relied upon portion of Finkelstein discloses only that the information is provided to someone remote from the user, that is, remote from the patient, and thus the patient is not informed of the rating of his/her answers to diary questions. *See* Col. 3, lines 17-20 and 41-43 (stating ". . .displaying the test results, response message and patient information at a remotely located diagnosis/evaluation station").

For these reasons, Appellants respectfully submit that claims 1, 6, and 7 are patentable over Finkelstein, as Finkelstein does not disclose each and every element of claim 1. With respect to claims 4, 5, 10, and 12-15, Appellants respectfully submit that

dependent claims, by definition, include all the limitations of the claims from which they depend, and thus cannot be anticipated if a parent claim is not. *See* 35 U.S.C. §112(4).

b. Claim 8

Claim 8 depends from claim 6. Claim 8 recites "allowing the user to adjust at least one indicator level by at least one level." The Final Office Action cites Finkelstein for the proposition that the "[a]lert parameters can be preset for any of the twenty-nine FVC test parameters." *See Col.* 7, lines 7-14. The Finkelstein alert parameters relate to alerting a medical professional of a problem based upon real physical test data obtained from a FVC test, not answers to symptom diary questions, which disclosure is relied upon in rejecting the claims from which claim 8 depends. Furthermore, the user who has entered the symptom data and been subject to the physical tests does not have the ability to change the threshold for the alert, as this is done by someone else. In Finkelstein, this is the physician who is remote from the information source, not the user who is the information source as that term is used in claim 8. Additionally, the alert parameters in Finkelstein are set in advance to cause a warning to be issued if the alert is triggered, which is the opposite of the recitation of claim 8 that allows for the indicator level to be changed after the assessment is completed.

Based upon the above, Appellant respectfully submits that claim 8 is patentable over Finkelstein, because Finkelstein does not disclose each and every element of claim 8.

c. Claims 16-18, 20-21, and 23-28

Claims 16, 17, 18, 20-21, and 23-28 relate to a method for accessing severity of asthma for a patient. The method recited in these claims includes the steps of transmitting a question to an individual, receiving an answer to the transmitted question from the individual, accumulating a score for at least one indicator based upon the received answer, repeating these steps for each question in a series of questions that make up the assessment, and transmitting at least one indicator level based on the at least one indicator score. According to this method, for each of the at least one indicator, there is at least answers to two questions that will result in the indicator.

Independent claim 16 recites "repeating steps a through c for each question in a series of questions that make up the assessment." Steps a through c, recite,

respectfully, asking a question of an individual, receiving an answer to the question, and accumulating a score for at least one indicator based upon the received answer. Claim 16 also recites "for each of the at least one indicator, there is at least answers to two questions that will result in the indicator."

Appellant respectfully submits that although Finkelstein may maintain answers to individual symptom diary questions over a period of days, Finkelstein does not teach, "accumulating a score for at least one indicator based upon the received answer." Furthermore, the wherein clause of claim 16 recites, "wherein for each of the at least one indicator, there is at least answers to *two* questions that will result in the indicator." (emphasis added). This language indicates that answers to different questions are combined to devise a grade according to a predetermined scale. Finkelstein, however, simply does not teach the combining of answers to different questions to devise a grade according to a predetermined scale. Therefore, Finkelstein does not anticipate claim 16, as Finkelstein does not teach each and every element of claim 16.

Appellant respectfully submits that dependent claims 17-18, 20-21, and 23-28 are also patentable, as by definition, they each include all the limitations of the claim from which they depend, and thus cannot be anticipated if their parent claim is not. *See* 35 U.S.C. § 112(4).

d. Claim 22

Claim 22 depends from claims 16 and 21. Claim 22 further recites an additional step wherein educational material tailored to the at least one indicator level of the patient is provided. For example, in at least one embodiment of the present invention, an education database is provided to present education information such as multimedia presentations about asthma. The education database includes elements that can be adapted to the user based upon the assessment results (for example, tailored to the at least one indicator level of the patient). *See* Application, page 12, paragraph 50. Finkelstein, however, simply does not teach providing educational material to a patient. Therefore, Appellant respectfully submits that claim 22 is patentable, as its features are not anticipated by Finkelstein.

B. Rejection of Claims under 35 U.S.C. §103(a)

i. Rejection of Claims 9 and 19 over Finkelstein

The Examiner rejected claims 9 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Finkelstein. Appellant respectfully submits that claims 9 and 19 are patentable over Finkelstein, as Finkelstein does not teach or suggest the elements of claims 9 and 19. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Claim 9 depends from claim 7, which in turn depends from claim 6. Claim 9 recites that "the at least one indicator includes at least one of a severity level, a compliance level, and a performance level." Claim 6 recites that an answer to a particular question increments a score for at least one indicator. Finkelstein discloses classifying a peak expiratory flow test result per guidelines established by the National Heart, Lung, and Blood Institute. *See* Finkelstein, Col. 6, lines 16-20. The peak expiratory flow test is a test to determine a physical characteristic of the patient, and does not include the patient answering any questions. The classification in Finkelstein is based upon a physical characteristic and not a series of answers to multiple questions as recited in Appellant's claims. The communication provided by the physician relates to the physician analysis of physical test results, and not entries made by the patient in response to the symptom diary questions. *See* Finkelstein, Col. 7, lines 21-37. Therefore, Appellant respectfully submits that claim 9 is patentable over Finkelstein, as Finkelstein does not teach or suggest the features of claim 9.

Claim 19 depends from claim 18. Claim 19 recites "personalizing the assessment questions based on the at least one answer received for each of the at least one background information question." The personalization could be including the person's name in the assessment question, for example, not the personalization discussed in paragraph 23 on page 6 of the Final Office Action, which discusses alert status and other concepts which appear to have nothing to do with the recitation of claim 19. Therefore, Appellant submits that claim 19 is patentable over Finkelstein, as Finkelstein does not teach or suggest the features of claim 19.

Appellant respectfully submits that claims 9 and 19 are patentable over Finkelstein in view of their dependence from claims submitted to be patentable over

Finkelstein and in view of the features argued above. *See* 35 U.S.C. §112(4). *See also In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

ii. Rejection of Claims over Finkelstein in view of Brown (U.S. Pat. No. 6,375,469)

Claims 11 and 35-40 have been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Finkelstein in view of Brown (U.S. Pat. No. 6,375,469). Appellant respectfully submits that these claims are patentable over Finkelstein in view of Brown '469, as neither Finkelstein nor Brown '469 either alone or in combination teaches or suggests the elements of these claims.

To establish a *prima facie* case of obviousness, one of the basic criteria that must be met is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine reference teachings. Further the teaching or suggestion to make the claimed combination must be found in the prior art, and not based on applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). To support a conclusion of obviousness, either the references must expressly or impliedly suggest the claimed invention or a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references must be provided. *See* MPEP § 2142. *See also Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

The claims are divided into four sub-groups (e: 11; f: 35 and 38-40; g: 36; and h: 37) that are submitted as being separately patentable. Sub-group e is separately patentable from sub-groups f-h, because claim 11 depends from claim 6 which is submitted as being separately patentable since the claims are of different scope and would not be obvious in view of each other. Sub-groups f-h are separately patentable from one another because it is not obvious to add either the particular types of indicators recited in claim 36 or allowing adjustment of the indicator level after the assessment has occurred as recited in claim 37 to the underlying independent claim 35. Claim 37 is patentable over claim 36, because it is not obvious to allow for adjustment of an indicator level.

a. Claim 11

Claim 11 depends from claim 6 through claims 7 and 10, and claim 11 further recites that the educational material includes multimedia presentations for the user. Appellant respectfully submits that claim 11 is patentable over Finkelstein in view of Brown '469 in light of its dependency from patentable claims 6 through 7 and 10, as Brown '469 does not rectify the missing teachings of Finkelstein as described above in Appellant's argument regarding independent claim 6, in section (8)(A)(b), *supra*. *See* 35 U.S.C. § 112(4).

b. Claims 35 and 38-40

Claims 35 and 38-40 recite a method for assessing the severity of asthma for a patient. The method includes "asking a plurality of questions, for each answer to one of said questions, adjusting the score for at least one indicator where said indicator is predetermined to relate to the question for which the answer was provided, determining an indicator level for each indicator based on comparing that indicator to a predetermined scale, and providing the indicator level for each indicator." Paragraph 29 of the Final Office Action is silent regarding these elements and as such has failed to set forth a proper rejection of claims 35-40.

The one step that is partially discussed in the Final Office Action is "setting a score for at least two indicators to zero." The alert parameters in Finkelstein are set for 29 FVC parameters, which as has been discussed above are physical measurements that are recorded by medical equipment and are not answers to questions. Therefore, alert parameters are not indicators, which as recited in claim 35 are tied to predetermined questions so that answers from those questions increase the indicator score. The entry of physical measurements in Finkelstein does not change the threshold for the alert levels, as those are fixed in advance of the test by the physician.

Brown '469 does not use the phrase "performance level," consequently Appellant is unsure of what is being referred to in paragraph 29 of the Final Office Action. Brown '469 teaches determining "[t]he patient's criticality." The patient's criticality measures the patient's compliance with the treatment regimen." *See* Brown '469, Col. 2, lines 64-65. Criticality includes "a criticality index that measures differences between actual health parameters of the patient ... and corresponding recommended health parameters

of the patient ... ." *See* Brown '469, Col. 6, lines 45-49. The health parameters include medical history data. *See* Brown '469, Col. 6, lines 37-40. Consequently, Brown '469 teaches at best just one indicator; however, that indicator is not based upon answers to questions that add to an indicator score but instead are differences between actual status of the patient and an ideal treatment status for the patient.

Thus, neither Finkelstein nor Brown '469 teaches multiple indicators let alone indicators that have a score based on answers to multiple questions that then are compared to a predetermined scale to determine the indicator level. Since neither teaches or suggests this, then a combination of the two is unable to teach this feature. The rationale ("the patient may use independently to determine how to better manage their health condition") for combining Finkelstein and Brown '469 are contrary to the disclosed systems/methods of these two patents since both disclosures make it clear that a physician is an activate participant from, for example, monitoring in Finkelstein to setting up the treatment plan in Brown '469.

Appellant respectfully submits that claim 35 is patentable over the alleged combination of Finkelstein and Brown '469, as the combination of Finkelstein and Brown '469 does not render this claim obvious. Appellant also respectfully submits that dependent claims 38-40, by definition, include all the limitations of the claims from which they depend, and thus cannot be anticipated if their parent claim is not. *See* 35 U.S.C. §112(4).

c. Claim 36

Claim 36 has been rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Finkelstein in view of Brown (U.S. Pat. No. 6,375,469). Appellant respectfully traverses this rejection.

Claim 36 depends from claim 35 wherein the at least two indicators include "at least one of a severity level, a compliance level, and a performance level." The Final Office Action asserts that Finkelstein provides for a plurality of alert parameters in which a level must be known in order to trigger an alert. The Office Action further asserts that Brown '469 teaches that measures for a compliance level and a performance level must be accumulated to assist in educating an asthma sufferer.

The Final Office Action has failed to establish a *prima facie* case of obviousness and has fundamentally erred in assessing the scope and content of the prior art. More specifically, for example, the Final Office Action asserts that Finkelstein provides for a plurality of alert parameters, in which a level must be known in order to trigger an alert.

These alert parameters in Finkelstein are set for twenty-nine FVC parameters. These FVC parameters are physical measurements (for example, measurements pertaining to airway dysfunction) that are recorded by medical equipment and are not answers to questions. *See, for example,* Finkelstein, col. 2, lines 49-52. Appellant respectfully submits that alert parameters are not indicators, which as recited in claim 35 (from which claim 36 depends) are tied to predetermined questions such that answers from those questions increase the indicator score.

Thus, Appellant respectfully submits that Finkelstein does not teach or suggest at least two indicators including at least one of a severity level, a compliance level, and a performance level, where the indicators are based on a plurality of questions, as reflected in claim 35 from which claim 36 depends.

The Final Office Action has also alleged that Brown '469 teaches that measures for a compliance level and a performance level must be accumulated to assist in educating an asthma sufferer. *See* Office Action at page 8. Appellant respectfully submits that Brown 469 simply does not mention a "performance level." Although Brown '469 does mention a compliance level, the compliance level in Brown '469 is not "predetermined to relate to the question for which the answer was provided," as in claim 35 (from which claim 36 depends) of the present invention. Brown '469 teaches patient criticality which measures the patient's compliance with the treatment regimen. *See* Brown '469, col. 2, lines 64-65. Brown '469 also teaches a health profile which includes a history of physical measurements of the patient such as blood glucose readings, for example. *See* Brown '469, col. 6, lines 35-39. In addition, Brown '469 teaches a treatment regiment, which is based on recommended health parameters of the patient. *See* Brown '469, col. 6, lines 46-48. A criticality means generates criticality by comparing the treatment regimen with the health profile. *See* Brown '469, col. 6, lines 42-43. Thus, the criticality in Brown '469 (which measures the patient's compliance with the treatment regimen) is not based on a patient's answers to questions, as in the

present invention. Rather, it is based on physical measurements of the patient and recommended health parameters of the patient.

Therefore, Appellant respectfully submits that there is nothing in Finkelstein or Brown '469 that would render the subject matter of claim 36 obvious, as neither Brown '469 nor Finkelstein either alone or in combination teaches or suggests the features of this claim.

d. Claim 37

Claim 37 has been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Finkelstein in view of Brown (U.S. Pat. No 6,375,469). Appellant respectfully traverses this rejection.

Claim 37 depends from claim 35 and further recites "allowing the user to adjust at least one of the indicator levels on the predetermined scale associated with that indicator." For example, if it is determined that a patient is suffering from "mild intermittent asthma," and the patient believes this diagnosis is inaccurate, the patient may adjust his level to "moderate persistent asthma." According to the Final Office Action, Finkelstein discloses a method in which a plurality of indicators (such as an alert level) may be changed dynamically. *See* Office Action, at page 9.

Appellant submits that Finkelstein does not teach or suggest the steps of claim 37, as the alert parameters in Finkelstein are tied to a threshold for either a current reading or a change. This is no predetermined scale, however, as recited in claim 37, on which to allow the user to change the indicator level. *See* Finkelstein, col. 7, lines 8-10.

Appellant further submits that although the alert parameters in Finkelstein can be preset for the twenty-nine FVC test parameters, the alert parameters relate to alerting a medical professional of a problem based upon physical test data obtained from an FVC test, not answers to symptom diary questions, as in claim 35, from which claim 37 depends. *See* Finkelstein, Col. 7, lines 7-14.

Further, in the present invention, the user is the information source, as the user is the party who is actually entering the information. *See* Application, Page 12, Paragraph 51 – Page 13, Paragraph 51. *See also*, Page 17, Paragraph 73. In Finkelstein, however, the user who has entered the symptom data and been subjected to the

physical tests does not have the ability to change the threshold for the alert, as this is done by the physician, a party who is remote from the information source (that is, a party who is remote from the user). Further still, the alert parameters in Finkelstein are set in advance of any assessment to cause a warning to be issued if the alert is triggered. In direct contrast, in the present invention, the user is allowed to alter the indicator level *after* the assessment is completed. *See* id.

Appellants respectfully submit that Brown '469 simply does not teach "allowing the user to adjust at least one of the indicator levels at least one level on the predetermined scale associated with that indicator," as recited in claim 37. As discussed above, Brown '469 teaches at best just one indicator, and that indicator is not based upon answers to questions that add to an indicator score as recited in claim 35 (from which claim 37 depends). As discussed above, Brown '469 teaches determining "[t]he patient's criticality." The patient's criticality measures the patient's compliance with the treatment regimen, i.e., differences between actual status of the patient and an ideal treatment status for the patient. *See* Brown '469, Col. 2, lines 64-65. Thus, Appellant respectfully submits that Brown '469 does not teach or suggest these features of claim 37.

Since neither Brown '469 nor Finkelstein teaches or suggests the features discussed above, then a combination of Brown '469 and Finkelstein is unable to teach these features. The rationale ("providing a robust assessment tool that a patient may use independently to determine how to better manage their health condition") for combining Finkelstein and Brown '469 are contrary to the disclosed methods of these two patents since both disclosures make it clear that a physician is an activate participant from, for example, monitoring in Finkelstein to setting up the treatment plan in Brown '469.

iii. Rejection of Claims over Finkelstein in view of Brown et al. (U.S. Pat. No. 5,879,163)

Claims 2 and 3 have been rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Finkelstein in view of U.S. Pat. No. 5,879,163 issued to Brown (Brown '163). Appellant respectfully submits that neither Brown '163 nor Finkelstein either alone or in combination teaches or suggests the features of these claims.

Claims 2 and 3 are submitted as being separately patentable. Claim 3 is separately patentable from claim 2 because it is not obvious to add the particular types of indicators in claim 3 to claim 2.

A teaching or suggestion to make a claimed combination must be found in the prior art, and not based on applicant's disclosure. *See In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991). To support a conclusion of obviousness, either the references must expressly or impliedly suggest the claimed invention or a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *See* MPEP § 2142. *See also Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

a. Claim 2

Claim 2 depends from claim 1 and recites a means for randomizing the order of questions asked by the questioning means wherein the accumulating means accumulates multiple scores for at least two indicators.

Again, the official action has failed to establish a prima facie case of obviousness and has fundamentally erred in assessing the scope and content of the prior art. Claim 2 clearly recites "wherein said accumulating means accumulates multiple scores for at least **two** indicators" (emphasis added). Thus, the accumulating means in claim 2 accumulates an indicator score for each of at least two indicators. This language indicates that answers to different questions are combined to devise a grade according to a predetermined scale.

According to the Final Office Action, Finkelstein teaches the accumulation of multiple scores for multiple indices. *See* Office Action at page 14. Appellant submits that Finkelstein simply does not teach the combining of answers to different questions to devise a grade according to a predetermined scale. Further, as Appellant has previously discussed, Finkelstein's alert conditions are based on FVC test parameters which provide physical measurement data, not answers to questions provided by a patient.

In Brown '163, the profile generator scores the answers received for each of the six subsets of questions in category 60, for example, and calculates six numbers between 1 and 10 that numerically indicate the value placed by an individual on

longevity, quality of life, and family life, etc. *See* Brown '163, col. 10, lines 1-7. Thus, each subset of answers corresponding to one of the subsets of questions is assigned a numerical value. Unlike claim 2 of the present invention, however, Brown '163 does not teach an accumulating means that accumulates multiple scores for at least **two** indicators (emphasis added).

Therefore, Appellant submits that the combination of Finkelstein and Brown '163 does not render claim 2 obvious, as the combination of these references does not teach or suggest all of the features of claim 2. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

b. Claim 3

Claim 3 depends from claim 2 and recites that the at least two indicators include a severity level, a compliance level, and a performance level, and the correlating means correlates each score to one of the at least two indicators.

The Final Office Action asserts that Finkelstein provides for a plurality of alert parameters in which a level must be known in order to trigger an alert. The Office Action further asserts that Brown '163 teaches that measures for a compliance level and a performance level must be accumulated to assist in educating an asthma sufferer. Appellant submits that Finkelstein does not teach or suggest that the indicators include a severity level, compliance level, and a performance level, as recited in claim 3.

As discussed above with respect to claim 2, Brown '163 does not teach an accumulating means that accumulates multiple scores for at least **two** indicators. Therefore, Brown '163 does not teach or suggest "wherein the at least two indicators include severity level, compliance level, and performance level," as recited in claim 3.

Therefore, Appellant submits that the combination of Finkelstein and Brown '163 does not render claim 3 obvious, as the combination of these references does not teach or suggest all of the features of claim 3. *See In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

9. Conclusion

In view of the foregoing, it is respectfully submitted that the Examiner's final rejections of the claims fail to establish

1) *prima facie* anticipation of claims 1, 4-7, 10, and 12-15; 8; 16-18, 20-21, and 23-28; and 22; based on Finkelstein,

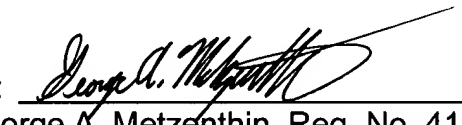
2) *prima facie* obviousness of claims 9 and 19 based on Finkelstein,

3) *prima facie* obviousness of claims 11; 35 and 38-40; 36; and 37 based on the combination of Finkelstein and Brown '469, and

4) *prima facie* obviousness of claims 2 and 3 based on the combination of Finkelstein and Brown '163.

None of the references, taken alone or in combination, teach or suggest all of the limitations of the claims. Withdrawal or reversal of the final rejections and allowance of all claims on appeal is respectfully requested.

Respectfully submitted,
CAHN & SAMUELS, L.L.P.

By: 

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Appendix I

1. A system for scoring an asthma severity for a patient based on information entered by a user regarding the patient comprising:

means for questioning the user regarding the patient,

means for accumulating a score for at least one indicator based on answers entered by the user to the questions,

means for correlating the accumulated score to at least one indicator level, and

means for informing the user of the at least one indicator level from said correlating means.

2. The system according to claim 1, further comprising means for randomizing the order of questions asked by said questioning means, and wherein said accumulating means accumulates multiple scores for at least two indicators.

3. The system according to claim 2, wherein the at least two indicators include severity level, compliance level, and performance level, and said correlating means correlates each score to one of the at least two indicators.

4. The system according to claim 1, further comprising means for providing a summary that includes the answers to the questions and the at least one indicator level.

5. The system according to claim 1, further comprising means for providing educational material to the user regarding asthma.

6. A method for assessing asthma patients comprising:

repeating the following for each question of an assessment

asking a question,

receiving an answer to the question, and

incrementing a score for at least one indicator based on the answer to the question;

correlating each of the at least one indicator score to a corresponding at least one indicator level; and

providing the at least one indicator level.

7. The method according to claim 6, wherein providing includes informing the user of the at least one indicator level.

8. The method according to claim 7, further comprising allowing the user to adjust at least one indicator level by at least one level.

9. The method according to claim 7, wherein the at least one indicator includes at least one of a severity level, a compliance level, and a performance level.

10. The method according to claim 7, further comprising providing educational material to the user regarding asthma.

11. The method according to claim 10, wherein providing educational material includes showing multimedia presentations to the user.

12. A system comprising:
a device having software to perform the method according to claim 6, and
a display in communication with said device.

13. The method according to claim 6, further comprising storing at least one of the answers and at least one indicator level.

14. A computer data signal embodied in a carrier wave readable by a computing system and encoding a computer program of instructions for executing a computer process performing the method recited in claim 6.

15. A computer-readable medium having computer-executable instructions for the method recited in claim 6.

16. A method for assessing severity of asthma for a patient comprising:
a) transmitting a question to an individual,
b) receiving an answer to the transmitted question from the individual,
c) accumulating a score for at least one indicator based upon the received answer,

d) repeating steps a through c for each question in a series of questions that make up the assessment, and

e) transmitting at least one indicator level based on the at least one indicator score to the individual; and

wherein for each of the at least one indicator, there is at least answers to two questions that will result in the indicator.

17. The method according to 16 further comprising storing the series of answers.

18. The method according to claim 16 further comprising:

transmitting at least one background information question regarding the patient to the individual, and

receiving an answer for each of the at least one background information question from the individual.

19. The method according to claim 18 further comprising personalizing the assessment questions based on the at least one answer received for each of the at least one background information question.

20. The method according to claim 16 further comprising providing a summary of the assessment to the individual.

21 The method according to claim 16 further comprising providing educational material to the user about asthma.

22. The method according to claim 21, wherein the providing educational material step includes material tailored to the at least one indicator level of the patient.

23. The method according to claim 16 further comprising providing asthma materials to the user.

24. The method according to claim 23, wherein the provided asthma material provided is based upon the at least one indicator level of the patient.

25. A computer data signal embodied in a carrier wave readable by a computing system and encoding a computer program of instructions for executing a computer process performing the method recited in claim 16.

26. A computer-readable medium having computer-executable instructions for the method recited in claim 16.

27. A system comprising:

a device having software to perform the method according to claim 16, and

a display in communication with said device.

28. The method according to 16 further comprising storing the at least one indicator level.

35. A method for assessing the severity of asthma for a patient comprising:

setting a score for at least two indicators to zero,

asking a plurality of questions,

for each answer to one of said questions, adjusting the score for at least one indicator where said indicator is predetermined to relate to the question for which the answer was provided,

determining an indicator level for each indicator based on comparing that indicator to a predetermined scale, and

providing the indicator level for each indicator.

36. The method according to claim 35, wherein the at least two indicators include at least one of a severity level, a compliance level, and a performance level.

37. The method according to claim 35, further comprising allowing the user to adjust at least one of the indicator levels at least one level on the predetermined scale associated with that indicator.

38. The method according to claim 35, further comprising storing the answers to the questions.

39. The method according to claim 35, further comprising:

asking at least one background information question regarding the patient to the individual, and

receiving an answer for each of the at least one background information question from the individual.

40. The method according to claim 35, further comprising providing educational material about asthma.